

**CELL TECH INTERNATIONAL INCORPORATED**

565 Century Court, Klamath Falls, Oregon 97601

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December 10, 2003

**CERTIFIED MAIL, RETURN  
RECEIPT REQUESTED**

Office of Nutritional Product, Labeling and  
Dietary Supplement (HFS 810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Notification of Product claims

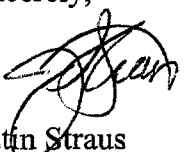
Dear Sir or Madam:

This letter serves as notification of the nutritional support label statements being made by Cell Tech located at 565 Century Court, Klamath Falls, OR 97601, in connection with products being marketed by Cell Tech. A list of the products and their respective nutritional support statements are listed in the enclosed Attachment "A".

The company hereby certifies that the information contained in this notice is complete and accurate, and that the company can substantiate the statements of nutritional support that are the subject of this notification letter.

If you have any questions, please feel free to contact the undersigned.

Sincerely,

  
Justin Straus  
Chief Operating Officer  
Cell Tech International Incorporated

Encl.

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## ATTACHMENT "A"

1. **Product: Super Q10**

A dietary supplement containing a proprietary blend of coenzyme Q10, Betatene® (carotenoid extract), essential oils (fennel, ginger, and cinnamon), and blue-green algae (*Aphanizomenon flos-aquae*).

**Statements of Nutritional Support:**

- Super Q10 combines premium antioxidants to boost cellular energy, counter free radical damage, support physical activity, promote periodontal health, support cardiovascular and immune systems and assist weight management.\*

2. **Product: Super Sprouts & Algae**

A dietary supplement containing a proprietary blend of wheat sprouts, Betatene® (carotenoid extracts), and blue-green algae (*Aphanizomenon flos-aquae*).

**Statements of Nutritional Support:**

- This unique product helps promote joint health and cleansing of cells and tissues to retain youthful vitality.\*

3. **Product: Original Formula Enzymes**

A dietary supplement containing a proprietary blend of amylase, lipase, protease, lactase, cellulase, blue-green algae (*Aphanizomenon flos-aquae*).

**Statements of Nutritional Support:**

- Cell Tech's plant-based enzymes do not replace the body's own natural digestive enzymes; but work with the body to break down fats, protein, carbohydrates, and fiber, thus relieving stress on the stomach and intestinal tract.\*
- Now, with Cell Tech's new extra-strength Super Blue Green® Enzymes your digestive system has more support than ever.\*
- Original Formula Enzymes are ideal for anyone who wants to support digestion and assimilation of nutrients, without the cayenne, ginger, or fennel contained in E-12 Super Enzymes.
- Enzymes may be taken with any cooked food to boost digestion.\*

4. **Product: Alpha Sun®**

A dietary supplement containing freeze-dried blue-green algae (*Aphanizomenon flos-aquae*).

**Statements of Nutritional Support:**

- Support all the normal functions of the human body, particularly digestion and elimination.\*
- Alpha Sun® is the whole, complete algae intended for the natural promotion of physical health and immune system support.\*

5. **Product: Omega Sun®**

A dietary supplement containing freeze-dried blue-green algae (*Aphanizomenon flos-aquae*).

**Statements of Nutritional Support:**

- These nutrients include amino acids, the building blocks of healthy nerve cells and neurotransmitters vital for proper brain function, and essential fatty acids (omega-3 and omega-6), which are necessary for cardiovascular health and many other aspects of wellness.\*
- Omega Sun helps maintain normal, healthy blood chemistry; it feeds the blood the feeds the brain. This highly nutritious supplement can be beneficial to central nervous system functioning, enhanced mental alertness and clarity, and emotional stability.\*
- Omega Sun® is Super Blue Green® Algae with the cell wall removed and is intended for the natural promotion of mental health and immune system support.\*

6. **Product: Super Q10**

A dietary supplement containing a proprietary blend of coenzyme Q10, Betatene® (carotenoid extract), essential oils (fennel, ginger, and cinnamon), and blue-green algae (*Aphanizomenon flos-aquae*).

**Statements of Nutritional Support:**

- Extensive studies show numerous benefits from this antioxidant, such as boosting the immune system, strengthening the heart, promoting stamina, and supporting weight loss.\*

7. **Product: Reality™**

A liquid dietary supplement containing water, vegetable glycerin, Omega Sun Super Blue-Green Algae, and natural apple flavoring. Reality is an energy drink concentrate with a wide array of phytonutrients from Super Blue-Green Algae.

**Statements of Nutritional Support:**

- A one-ounce serving of Reality equals three capsules of Omega Sun® algae and contributes to better mental performance, focus, and mood.\*
- Reality will give your mind and body a boost, not a buzz.\*

8. **Product: Resistance™**

A liquid dietary supplement containing water, vegetable glycerin, Omega Sun Super Blue-Green Algae, WGP (TM) beta-glucan, and natural cinnamon flavoring. Resistance is an energy drink concentrate with a wide array of phytonutrients from blue-green algae and natural immune system support from beta-glucan.

**Statements of Nutritional Support:**

- Resistance is a liquid concentrate of Super Blue Green Omega Sun algae and WGP™ Beta Glucan, one of the most powerful immune system supports you can get.\*

- With a broad array of micronutrients (and NO preservatives or stimulants), Resistance is a delicious and refreshing way to support your body's natural defenses.\*
- A one-ounce serving of Resistance also contributes to better mental performance, focus, and mood.\*
- In addition to vitamins, minerals, and phytonutrients, Resistance provides a wide range of essential amino acids, which feed and enhance brain activity.\*
- Resistance will help boost your mind and guard your body.\*
- Resistance provides natural support for your immune system.\*
- Whether you add it to your favorite beverage or drink it straight, the cinnamon flavor makes Resistance a tasty and refreshing way to enhance your body's natural defenses.\*

Also see \* 9. **Product: Grape Synergy<sup>TM</sup>**  
 docket 875-0163

A dietary supplement containing grape seed extract, Super Blue-Green Algae, grape skin extract, Japanese knotweed extract, vitamin C extracts and vitamin E (excipients are rice flour, magnesium stearate, silicon dioxide) in a vegetarian capsule. Grape Synergy is an antioxidant product intended to neutralize free radicals.

**Statements of Nutritional Support:**

- Red grapes are known to contain many beneficial nutrients, and grape skin extracts are now widely used in the nutraceutical and pharmaceutical industries for cardiovascular support.\*
- Other beneficial phytonutrients (plant-based nutrients) found in grape seed and grape skin extract include certain bioflavonoids, polyphenols, and trans-resveratrol, all of which have a highly beneficial impact on circulation and healthy LDL cholesterol and help keep blood thrombocytes flowing freely and normally.\*
- Support flexibility of connective tissue (skin and joints)\*
- Maintain cardiovascular health, circulation, and cell vitality\*
- Improve visual acuity, including night vision, and support eye health\*
- Stimulate vascular health of legs and support healthy blood pressure levels\*

**10. Product: New Seasons<sup>TM</sup>**

A dietary supplement system consisting of two formulas as listed below.

**Herbal Formula**

A dietary supplement containing rice bran, Jerusalem artichoke tubers, milk thistle seed, pumpkin seed, turmeric root, wheat grass, aloe vera gel, amylase, burdock root, dandelion root, *Echinacea purpurea* root, fennel seed, plantain leaf, cabbage juice powder, cinnamon bark, clove flowerbuds, garlic bulb, ginger rhizome, thyme leaves, blue-green algae (*Aphanizomenon flos-aquae*), cayenne pepper, protease, black walnut leaf, cat's claw bark, cellulase, centaury herb, elecampane root, fenugreek seed, gentian root, grapefruit seed extract, licorice root, yellow dock root, and lipase.

### **Fiber Formula**

A dietary supplement containing oat fiber, apple fiber, beet root fiber, pea fiber, acacia gum, aloe vera gel, apple pectin, barberry root bark, cascara sagrada bark, turmeric root, Irish moss algae, konjac root glucomannan, slippery elm bark, wheat grass, cabbage juice powder, protease, blue-green algae (*Aphanizomenon flos-aquae*), amylase, cellulase, and lipase.

#### **Statements of Nutritional Support:**

- The New Seasons Cleansing System—formulated with SBGA, specially selected herbs, and other natural ingredients—helps your body's natural detoxification systems work their best.

### 11. **Contain**<sup>TM</sup>

A dietary supplement containing a proprietary blend of: alginate, sodium bicarbonate, calcium carbonate, enzyme blend (protease, protease BC, Lipase, and amylase) and freeze-dried blue-green algae (*Aphanizomenon flos aquae*).

#### **Statements of Nutritional Support:**

- These pleasant-tasting chewable tablets are made with just the right combination of alginate (algae extract), enzymes, and other soothing natural ingredients that join forces to “contain” stomach acid.\*
- The enzymes in the formulation aid in the efficient breakdown of food, thereby contributing to healthy and effective digestion.\*

### 12. **Product: OsteoSun**<sup>TM</sup>

A dietary supplement containing freeze-dried blue-green algae (*Aphanizomenon flos-aquae*) and red yeast rice (*Monascus purpureus* Went).

#### **Statements of Nutritional Support:**

- Moms will appreciate a gift of OsteoSun, for natural bone health.\*
- OsteoSun, which contains a patented form of red yeast rice and Omega Sun, is an all natural non-calcium supplement that helps support bone health.\*
- Helps promote bone health\*
- While calcium can keep existing bone strong, OsteoSun not only helps strengthen existing bone, but it can also help regenerate lost bone and build new bone.\*

### 13. **Product: ImmuSun**<sup>TM</sup>

A dietary supplement containing WGP<sup>TM</sup> beta 1,3 / 1,6 glucan.

#### **Statements of Nutritional Support:**

- Taken daily as part of an overall healthful regimen, ImmuSun<sup>TM</sup> can help the immune system maintain peak performance.\*
- ImmuSun's WGP beta glucan is a proven immune system enhancer.\*
- ImmuSun has been shown to fortify your immune system.\*
- Provides enhanced support for the body's immune system\*
- These studies have proven WGP beta glucan's ability to activate macrophages, a type of white blood cell that is the body's first line of defense.\*

- Macrophages circulate throughout the body engulfing and digesting foreign antigens, thus triggering a cascading effect that mobilizes the body's arsenal of defenses.\*